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PATENT
Attorney Docket No. LEX-002C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies *et al.*
SERIAL NO.: 10/005,212 GROUP NO.: 1646
FILING DATE: December 4, 2001 EXAMINER: P. M. Mertz
TITLE: HETERODIMERIC FUSION PROTEINS USEFUL FOR TARGETED IMMUNE
THERAPY AND GENERAL IMMUNE STIMULATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**

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- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

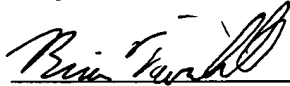
It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants believe no additional fee is required for entry and consideration of this paper. If an additional fee is required, please charge Deposit Account 20-0531.

Date: March 8, 2004
Reg. No. 48,645
Tel. No.: (617) 248-7697
Fax No.: (617) 248-7100

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Respectfully submitted,



Brian A. Fairchild, Ph.D.
Attorney for Applicants
Testa, Hurwitz & Thibault, LLP
125 High Street
Boston, Massachusetts 02110



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CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on this 8th day of March, 2004.

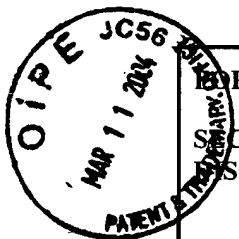

Anna-Karin Kuliga

Commissioner for Patents
P.O. Box 1450
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Attached hereto is/are:

1. Transmittal Form (1 page);
2. Fee Transmittal (1 page);
3. A check in the amount of \$180.00;
4. Second Supplemental Information Disclosure Statement (2 pages);
5. Form PTO-1449 (7 pages);
6. Copies of cited references (A60-95, B88-B106, and C170-C238); and
7. A return receipt postcard.

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FORM PTO - 1449

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U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A60	4,703,008	10/27/87	Lin			
	A61	5,441,868	8/15/95	Lin			
	A62	5,547,933	8/20/96	Lin			
	A63	5,618,698	4/8/97	Lin			
	A64	5,624,821	4/29/97	Winter et al.			
	A65	5,679,543	10/21/97	Lawlis			
	A66	5,688,679	11/18/97	Powell			
	A67	5,756,349	5/26/98	Lin			
	A68	5,856,298	1/5/99	Strickland			
	A69	5,888,772	3/30/99	Okasinski et al.			
	A70	5,955,422	9/21/99	Lin			
	A71	6,231,536	5/15/01	Lentz			
	A72	6,284,536	9/4/01	Morrison et al.			
	A73	6,335,176	1/1/02	Inglese et al.			
	A74	6,340,742	1/22/02	Burg et al.			
	A75	6,444,792	9/3/02	Gray et al.			
	A76	6,475,717	11/5/02	Enssle et al.			
	A77	6,485,726	11/26/02	Blumberg et al.			
	A78	6,506,405	1/14/03	Desai et al.			
	A79	6,583,272	6/24/03	Bailon			
	A80	6,586,398	7/1/03	Kinstler et al.			
	A81	6,617,135	9/9/03	Gillies et al.			
	A82	2001/0053539	12/20/01	Lauffer et al.			
	A83	2002/0081664	6/27/02	Lo et al.			
	A84	2002/0142374	10/3/02	Gallo et al.			
	A85	2002/0147311	10/10/02	Gillies et al.			
	A86	2002/0192222	12/19/02	Blumberg et al.			
	A87	2002/0193570	12/19/02	Gillies et al.			
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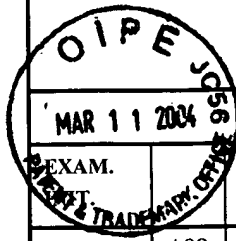
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EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A88	2003/0003529	1/2/03	Bayer		
	A89	2003/0044423	3/6/03	Gillies et al.		
	A90	2003/0049227	3/13/03	Gillies et al.		
	A91	2003/0105294	6/5/03	Gillies et al.		
	A92	2003/0012789	1/6/03	Blumberg et al.		
	A93	2003/0157054	8/21/03	Gillies et al.		
	A94	2003/0166163	9/4/03	Gillies		
	A95	2003/0166877	9/4/03	Gillies et al.		

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FOREIGN PATENT DOCUMENTS

EXAM INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B88	0 640 619 A1	3/1/95	EP				Y
	B89	0 668 353 A1	8/23/95	EP				Y
	B90	1 088 888 A1	4/4/01	EP				Y
	B91	WO 94/24160	10/27/94	PCT				Y
	B92	WO 94/25055	11/10/94	PCT				Y
	B93	WO 97/43316	11/20/97	PCT				Y
	B94	WO 99/66054	12/23/99	PCT				Y
	B95	WO 00/24893	5/4/00	PCT				
	B96	WO 00/68376	11/16/00	PCT				Y
	B97	WO 01/36489	5/25/01	PCT				Y
	B98	WO 01/58957	8/16/01	PCT				
	B99	WO 02/02143	1/10/02	PCT				
	B100	WO 02/066514	8/29/02	PCT				Y
	B101	WO 02/072605	9/19/02	PCT				
	B102	WO 02/079232	10/10/02	PCT				
	B103	WO 02/079415	10/10/02	PCT				
	B104	WO 02/090566	11/14/02	PCT				

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	B105	WO 03/048334	6/12/03	PCT		
	B106	WO 03/077834	9/25/03	PCT		Y
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)					
	C170	Angal et al., (1993), "A Single Amino Acid Substitution Abolishes the Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody," <u>Molecular Immunology</u> , 30(1):105-108.				
	C171	Batra et al., (1993), "Insertion of Constant Region Domains of Human IgG1 into CD4-PE40 Increases Its Plasma Half-Life," <u>Mol. Immunol.</u> , 30(4):379-386.				
	C172	Becker et al., (1996), "Long-lived and Transferable Tumor Immunity in Mice after Targeted Interleukin-2 Therapy," <u>J Clin Invest.</u> , 98(12):2801-2804.				
	C173	Becker et al., (1996), "T Cell-mediated Eradication of Murine Metastatic Melanoma Induced by Targeted Interleukin-2 Therapy," <u>J Exp. Med.</u> , 183(50):2361-6.				
	C174	Bitonti et al., (2002), "Transepithelial Absorption of an Erythropoietin-Fc Fusion Protein After Delivery to the Central Airways," <u>Respiratory Drug Delivery</u> , 8:309-312.				
	C175	Boissel et al., (1993), "Erythropoietin Structure-Function Relationships: Mutant Proteins that Test a Model of Tertiary Structure," <u>The Journal of Biological Chemistry</u> , 268(21):15983-15993.				
	C176	Briggs et al., (1974), "Hepatic Clearance of Intact and desialylated Erythropoietin," <u>American Journal of Physiology</u> , 227(6):1385-1388.				
	C177	Chuang et al., (1994), "Alteration of Lymphocyte Microtubule Assembly, Cytotoxicity, and Activation by the Anticancer Drug Taxol," <u>Cancer Research</u> , 54:1286-1291.				
	C178	Cruse et al., (1995), <u>Illustrated Dictionary of Immunology</u> , CRC Press, NY, p.156-7.				
	C179	Darling et al., (2002), "Glycosylation of Erythropoietin Affects Receptor Binding Kinetics: Role of Electrostatic Interactions," <u>Biochemistry</u> , 41:14524-14531.				
	C180	Davis et al., (2003), "Immunocytokines: Amplification of Anti-cancer Immunity," <u>Cancer Immunol. Immunother.</u> , 52:297-308.				
	C181	Dolman et al., (1998), "Suppression of Human Prostate Carcinoma Metastases in Severe Combined Immunodeficient Mice by Interleukin 2 Immunocytokine Therapy," <u>Clin Cancer Res.</u> , 4(10):2551-7.				
	C182	Duncan et al., (1988), "The Binding Site for C1q on IgG," <u>Nature</u> , 332:738-740.				
	C183	Egrie et al., (2001), "Development and Characterization of Novel Erythropoiesis Stimulating Protein (NESP)," <u>Nephrol. Dial. Transplant.</u> , 16:3-13.				
	C184	Elliott et al., (1997), "Mapping of the Active Site of Recombinant Human Erythropoietin," <u>Blood</u> , 89(2):493-502.				
	C185	Fibi et al., (1995), "N- and O-Glycosylation Muteins of Recombinant Human Erythropoietin Secreted From BHK-21 Cells," <u>Blood</u> , 85(5):1229-1236.				
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	C186		Frost et al., (1997), "A Phase I/IB Trial of Murine Monoclonal Anti GD2 Antibody 14.G2a Plus Interleukin-2 in Children with Refractory Neuroblastoma," <u>Cancer</u> , 80:317-33.			
	C187		Gan et al., (1999), "Specific enzyme-linked Immunosorbent Assays for Quantitation of Antibody-cytokine Fusion Proteins," <u>Clin. Diagn. Lab. Immunol.</u> , 6(2):236-42.			
	C188		Gillies et al., (1991), "Expression of Genetically Engineered Immunoconjugates of Lymphotoxin and a Chimeric Anti-ganglioside GD2 Antibody," <u>Hybridoma</u> , 10(3):347-56.			
	C189		Gillies et al., (2002), "Bi-functional Cytokine Fusion Proteins for Gene Therapy and Antibody-targeted Treatment of Cancer," <u>Cancer Immunol. Immunother.</u> , 51(8):449-60.			
	C190		Gillies et al., (2002), "Improved Circulating Half-life and eRfficacy of an Antibody-interleukin 2 Immunocytokine Based on Reduced Intracellular Proteolysis," <u>Clin. Cancer Res.</u> , 8(1):210-6.			
	C191		Greene et al., (1975), Neuronal Properties of Hybrid Neuroblastoma X Sympathetic Ganglion Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 72(12):4923-4927.			
	C192		Hammerling et al. (1996), "In Vitro Bioassay for Human Erythropoietin based on Proliferative Stimulation of an Erythroid Cell Line and Analysis of Carbohydrate-dependent Microheterogeneity," <u>Journal of Pharmaceutical and Biomedical Analysis</u> , 14:1455-1469.			
	C193		Hank et al., (1996), "Activation of Human Effector Cells by a Tumor Reactive Recombinant Anti-ganglioside GD2 Interleukin-2 Fusion Protein (ch14.18-IL2)," <u>Clin Cancer Res.</u> , 2(12):1951-9.			
	C194		Hank et al., (2003), "Determination of peak serum levels and immune response to the humanized anti-ganglioside antibody-interleukin-2 immunocytokine," <u>Methods Mol. Med.</u> , 85:123-31.			
	C195		Haraguchi, (1994), "Isolation of GD3 Synthase Gene by Expression Cloning of GM3 α -2,8-sialyltransferase Cdna using anti-GD2 Monoclonal Antibody," <u>Proc. Natl. Acad. Sci. USA</u> , 91(22):10455-9.			
	C196		Harris, (1995), "Processing of C-terminal Lysine and Arginine Residues of Proteins Isolated from Mammalian Cell Culture," <u>J. Chromatogr. A</u> , 705:129-134.			
	C197		Harvill et al., (1995), "An IgG3-IL2 Fusion Protein Activates Complement, Binds FcYRI, Generates LAK Activity and Shows Enhanced Binding to the High Affinity IL-2R," <u>Immunotech.</u> , 1:95-105.			
	C198		Hezareh et al, (2001), "Effector Function Activities of a Panel of Mutants of a Broadly Neutralizing Antibody against Human Immunodeficiency Virus Type 1," <u>J. Virol.</u> , 75(24):12161-8.			
	C199		Idusogie et al., (2000), "Mapping of the C1q Binding Site on Rituxan, a Chimeric Antibody with a Human IgG1 Fc," <u>J. Immunol.</u> , 164(8):4178-4184.			
	C200		Imboden et al., (2001), "The Level of MHC Class I Expression on Murine Adenocarcinoma Can Change the Antitumor Effector Mechanism of Immunocytokine Therapy," <u>Cancer Res.</u> , 61(4):1500-7.			
	C201		Kato et al., (1997), "Mechanism for the Nonlinear Pharmacokinetics of Erythropoietin in Rats," <u>The Journal of Pharmacology and Experimental Therapeutics</u> , 283:520-527.			
	C202		Kato et al., (1998), "Pharmacokinetics of Erythropoietin in Genetically Anemic Mice," <u>Drug Metabolism and Disposition</u> , 26:126-131.			
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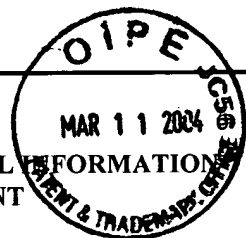
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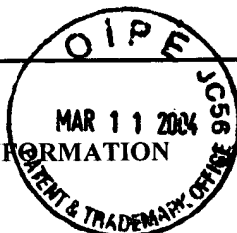


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EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	C203	Kitamura et al. (1989), "Establishment and Characterization of a Unique Human Cell Line that Proliferates Dependently on GM-CSF, IL-3, or Erythropoietin," <u>Journal of Cellular Physiology</u> , 140:323-334.					
	C204	Kushner et al., (2001), "Phase II Trial of the Anti-GD2 Monoclonal-macrophage-colony-stimulating Factor for Neuroblastoma," <u>J. Clin. Oncol.</u> , 19:4189-94.					
	C205	Locatelli et al., (2001), "Darbepoetin alfa Amgen," <u>Current Opinion in Investigational Drugs</u> , 2:1097-1104.					
	C206	Lode et al., (2000), "What to do with Targeted IL-2," <u>Drugs Today</u> , 36(5):321-36.					
	C207	Lode et al., (2000), "Melanoma Immunotherapy by Targeted Il-2 Depends on CD4(+) T-cell Help Mediated by CD40/CD40L Interaction," <u>J. Clin. Invest.</u> , 105(11):1623-30.					
	C208	Macedougall, (2002), "Optimizing the Use of Erythropoietic Agents—Pharmacokinetic and Pharmacodynamic Considerations," <u>Nephrol. Dial. Transplant.</u> , 17:66-70.					
	C209	Metelitsa et al., (2002), "Antidisialoganglioside/granulocyte Macrophage-colony-stimulating Factor Fusion Protein Facilitates Neutrophil Antibody-dependent Cellular Cytotoxicity and Depends on FcγRII (CD32) and Mac-1 (CD11b/CD18) for Enhanced Effector Cell Adhesion and Azurophil Granule Exocytosis," <u>Blood</u> , 99(11):4166-73.					
	C210	Mueller et al. (1997), "Humanized Porcine VCAM-specific Monoclonal Antibodies with Chimeric IgG2/G4 Constant Regions Block Human Leukocyte Binding to Porcine Endothelial Cells," <u>Molecular Immunology</u> , 34(6):441-452.					
	C211	Mullins et al. (1997), "Taxol-mediated Changes in Fibrosarcoma-induced Immune Cell Function: Modulation of Antitumor Activities," <u>Cancer Immunol. Immunother.</u> , 45:20-28.					
	C212	Naramura et al., "Mechanisms of Cellular Cytotoxicity Mediated by a Recombinant Antibody-IL2 Fusion Protein against Human Melanoma Cells," <u>Immunology Letters</u> , 39(1):91-9.					
	C213	Neal et al. (2003), "NXS2 Murine Neuroblastomas Express Increased Levels of MHC Class I Antigens upon Recurrence Following NK-dependent Immunotherapy," <u>Cancer Immunol Immunother.</u> , 53:41-52.					
	C214	Ngo et al., (1994), "The Protein Folding Problem and Tertiary Structure Prediction," pp. 433-440 and 492-495, Birkhauser Boston.					
	C215	Niethammer et al., (2002) "An oral DNA Vaccine against Human Carcinoembryonic Antigen (CEA) Prevents Growth and Dissemination of Lewis Lung Carcinoma in CEA Transgenic Mice," <u>Vaccine</u> , 20:421-9.					
	C216	Niethammer et al., (2001) "Targeted Interleukin 2 Therapy Enhances Protective Immunity Induced by an Autologous Murine Melanoma," <u>Cancer Res.</u> , 61(16):6178-84.					
	C217	Nimtz et al., (1993) Structures of Sialylated Oligosaccharides of Human Erythropoietin Expressed in Recombinant BHK-21 Cells," <u>Eur. J. Biochem.</u> , 213:39-56.					
	C218	Pancook et al., (1996), "Eradication of Established Hepatic Human Neuroblastoma Metastases in Mice with Severe Combined Immunodeficiency by Antibody-targeted Interleukin-2," <u>Cancer Immunol. Immunother.</u> , 42(2):88-92.					
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	C219	Park et al., (2000), "Efficiency of Promoter and Cell line in High-level Expression of Erythropoietin," <u>Biotechnol. Appl. Biochem.</u> , 32:167-172.					
	C220	Reisfeld et al., (1996), "Antibody-interleukin 2 Fusion Proteins: A New Approach to Cancer Therapy," <u>J Clin Lab Anal.</u> , 10(3):160-6.					
	C221	Reisfeld et al., (1996), "Involvement of B Lymphocytes in the Growth Inhibition of Human Pulmonary Melanoma Metastases in Athymic nu/nu Mice by an Antibody-lymphotoxin Fusion Protein," <u>Cancer Res.</u> , 56(8):1707-12.					
	C222	Ruehlmann et al., (2001), "MIG (CIXCL9) Chemokine Gene Therapy Combines with Antibody-cytokine Fusion Protein to Suppress Growth and Dissemination of Murine Colon Carcinoma," <u>Cancer Res.</u> , 61(23):8498-503.					
	C223	Sabzevari et al., (1994), "A Recombinant Antibody-interleukin 2 Fusion Protein Suppresses Growth of Hepatic Human Severe Combined Immunodeficiency Mice," <u>Proc. Natl. Acad. Sci. USA</u> , 91(20):9626-30.					
	C224	Seidenfeld et al., (2001), "Epoietin Treatment of Anemia Associated with Cancer Therapy: A Systematic Review and Meta-analysis of controlled Clinical Trials," <u>Journal of National Cancer Institute</u> , 93:1204-1214.					
	C225	Shinkawa et al., (2003), "The Absence of Fucose but Not the Presence of Galactose or Bisecting N-Acetylglucosamine of Human IgG1 Complex-type Oligosaccharides Shows the Critical Role of Enhancing Antibody-dependent Cellular Cytotoxicity," <u>J. Biol. Chem.</u> , 278:3466-3473.					
	C226	Spiekermann et al., (2002), "Receptor-mediated Immunoglobulin G Transport Across Mucosal Barriers in Adult Life: Functional Expression of FcRn in the Mammalian Lung," <u>J. Exp. Med.</u> , 196:303-310.					
	C227	Strom et al., (1996), "Therapeutic Approach to Organ Transplantation," <u>Therapeutic Immunology</u> , Blackwell Science, Chapter 36, pp. 451-456.					
	C228	Syed et al., (1998), "Efficiency of Signaling through Cytokine Receptors Depends Critically on Receptor Orientation," <u>Nature</u> , 395:511-516.					
	C229	Thommesen et al., (2000), "Lysine 322 in the Human IgG3 CH2 Domain is Crucial for Antibody Dependent Complement Activation," <u>Mol. Immunol.</u> , 37(16):995-1004.					
	C230	Wells, (1990), "Additivity of Mutational Effect in Proteins," <u>Biochemistry</u> , 29(37):8509-8517.					
	C231	Wen et al., (1993), "Erythropoietin Structure-Function Relationships: High Degree of Sequence Homology Among Mammals," <u>Blood</u> , 82(5):1507-1516.					
	C232	Xiang et al., (1998), "Induction of Persistent Tumor-protective Immunity in Mice Cured of Established Colon Carcinoma Metastases," <u>Cancer Research</u> , 58(17):3918-3925.					
	C233	Xiang et al., (1999) "T Cell Memory against Colon Carcinoma is Long-lived in the Absence of Antigen," <u>J. Immunol.</u> , 163(7):3676-83.					
	C234	Xiang et al., (2001), "A Dual Function DNA Vaccine Encoding Carcinoembryonic Antigen and CD40 Ligand Trimer induces T Cell-mediated Protective Immunity Against Colon Cancer in Carcinoembryonic Antigen-Transgenic Mice," <u>J Immunol.</u> , 167(8):4560-5.					
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EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	C235		Xiang et al., (2001), "Protective Immunity Against Human Carcinoembryonic Antigen (CEA) Induced by an Oral DNA Vaccine in CEA-transgenic Mice," <u>Clin Cancer Res.</u> , 7(3 Supp):S856-S864.			
	C236		Xu et al., (1994), "Residue at Position 331 in the IgG1 and IgG4 CH2 Domains Contributes to Their Differential Ability to Bind and Activate Complement," <u>J. Biol. Chem.</u> , 269(5):3469-3474.			
	C237		Yu et al., (1998), "Phase I Trial of a Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 in Patients with Refractory Neuroblastoma and Osteosarcoma," <u>J. Clin. Oncol.</u> , 16(6):2169-80.			
	C238		Zagozdzon et al. (1999), "Potentiation of Antitumor Effect of IL-12 in Combination with Paclitaxel in Murine Melanoma Model In Vivo," <u>International Journal of Molecular Medicine</u> , 4:645-648.			
EXAMINER			DATE CONSIDERED			

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